

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CAREDX, INC.)	
)	
and)	
)	
THE BOARD OF TRUSTEES OF THE)	
LELAND STANFORD JUNIOR)	C.A. No. 19-567-CFC
UNIVERSITY,)	
Plaintiffs,)	JURY TRIAL DEMANDED
)	
v.)	
)	
NATERA, INC.,)	
)	
Defendant.)	

PLAINTIFFS' NOTICE OF SUBSEQUENT AUTHORITY

Pursuant to D. Del. L.R. 7.1.2(b), Plaintiffs CareDx, Inc. and The Board of Trustees of the Leland Stanford Junior University (collectively "Plaintiffs") respectfully submit this Notice of Subsequent Authority in support of their opposition (D.I. 15) to Defendant's Motion to Dismiss (D.I. 9). That motion asserts that the two Stanford patents-in-suit are invalid because they allegedly do not claim patentable subject matter.

Following submission of Plaintiffs' opposition, the Federal Circuit issued three new precedential decisions relevant to this motion. As Plaintiffs explained in their opposition, Defendant's motion is so weak that its only apparent purpose is to delay this competitor litigation. This important case for CareDx was filed back in March and discovery has not opened and a schedule has not been set. These three new decisions confirm this point vividly.

In *Cellspin Soft, Inc. v. Fitbit, Inc.*, 927 F.3d 1306 (Fed. Cir. 2019), the Federal Circuit vacated the district court's grant of a motion to dismiss seeking invalidation of the patents for failing to claim patentable subject matter. The Federal Circuit concluded that the district court had mistakenly found that the ordered combination of steps did not add inventiveness to the ineligible

abstract idea. 927 F.3d at 1317-18. In reaching this conclusion, the Federal Circuit rejected the district court's assumption that the inventiveness of such subject matter had to be described in the specification: "[a]s long as what makes the claims inventive is recited by the claims, the specification need not expressly list all the reasons why this claimed structure is unconventional...Cellspin made specific, plausible factual allegations about why aspects of its claimed inventions were not conventional." *Id.* In addition, the Federal Circuit noted that the prior art included "inferior" attempts at utilizing the allegedly unpatentable subject matter, and credited the patentee's allegations that the claimed subject matter provided something beyond the unpatentable subject matter by improving upon these prior attempts. *Id.* at 1317. Finally, the Federal Circuit in *Cellspin* also confirmed that all issued patents are presumed to be directed to patent-eligible subject matter. *Id.* at 1319 ("To the extent the district court departed from this principle by concluding that issued patents are presumed *valid* but not presumed *patent eligible*, it was wrong to do so." (emphasis in original)).

Cellspin vividly highlights the weakness of Natera's motion to dismiss. Natera asserts that the claims "rest entirely on observing" the correlation between donor-specific cell-free DNA and organ rejection, which it characterizes as a natural phenomenon. D.I. 10 at 1. The specifications of the asserted patents, however, explain in detail how prior artists had long known of this correlation but had failed to successfully utilize it, and further explain how the claimed methods improved upon these prior failed attempts. *See, e.g.*, D.I. 1-1 at 7:55-8:58, 15:10-15. The specifications of the asserted patents thus highlight the inventiveness of the claims independent of the alleged natural phenomenon and, even if they did not, under *Cellspin* that would be no reason to grant Natera's motion. Further, as in *Cellspin*, Plaintiffs' pleading (including the materials incorporated into it, such as the specifications of the asserted patents) shows that the prior art failed

to solve the problem despite attempting to leverage the allegedly unpatentable subject matter. Thus the asserted patents, like those at issue in *Cellspin*, necessarily added inventive contributions.

In *Genetic Veterinary Sciences Inc. v. Laboklin GmbH & Co. KG*, No. 2018-2056, 2019 WL 3756316 (Fed. Cir. July 29, 2019), by contrast, the Federal Circuit upheld a district court's grant of JMOL invalidating claims for failing to claim patentable subject matter. The Federal Circuit explained that "the plain language of claim 1 demonstrates that it is directed to nothing more than 'observing or identifying' the natural phenomenon of a mutation in the SUV39H2 gene." 2019 WL 3756316, at *9. The Federal Circuit also found that "[t]he Asserted Claims do not recite an inventive concept that transforms the observation of a natural phenomenon into a patentable invention." *Id.* at *10. In reaching this conclusion, the Federal Circuit relied in part upon expert testimony. *Id.* ("[I]nstructive to our analysis is that LABOKLIN's expert agreed that the genotyping method in claim 1 uses conventional or known laboratory techniques to observe the newly discovered mutation in the SUV39H2 at position 972.").

Genetic Veterinary exemplifies the opposite of the facts in the case at bar. There, the patent was all about the discovery of a natural phenomenon (a mutation of a particular gene), and observation of that discovery involved mere routine techniques (a conclusion that the Federal Circuit reached only by relying upon expert evidence). Here, the patents-in-suit do not claim to have discovered the alleged natural phenomenon. Rather, the patents acknowledge that prior artists were aware of the alleged natural phenomenon, and explain how they failed at trying to apply it. *See, e.g.*, D.I. 1-1 at 7:55-8:58. The inventiveness of the patents is thus in their solution to the unsolved problem of how to practically apply the alleged natural phenomenon. That is textbook patentable subject matter.

Finally, in *Chamberlain Group, Inc. v. Techtronic Indus. Co.*, No. 2018-2103, 2019 WL 3938278 (Fed. Cir. Aug. 21, 2019), as in *Genetic Veterinary*, the Federal Circuit held a patent was invalid for claiming unpatentable subject matter because the only inventive aspect of the claims was the unpatentable abstract idea. As the Federal Circuit explained, “wireless transmission is the only aspect of the claims that CGI points to as allegedly inventive over the prior art.” 2019 WL 3938278, at *5. The Federal Circuit rejected the patentee’s position because “[w]ireless communication cannot be an inventive concept here, because it is the abstract idea that the claims are directed to.” *Id.* *Chamberlain Group* thus illustrates that, when the inventive aspect is the unpatentable subject matter, the claims are invalid. Here, the inventive aspect is a creative new way of *applying* the natural law. That is the opposite of *Chamberlain Group*.

All three of these new Federal Circuit decisions confirm that patents—like the asserted patents—that focus on a new combination of techniques to apply a natural phenomenon, as opposed to the natural phenomenon itself, are subject matter eligible. Accordingly, Natera’s motion to dismiss should be denied, and this competitor case should move forward.

Dated: August 23, 2019

Respectfully submitted,

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